APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mohan Krishnan et al.	Examiner: Terri L. Smith
Serial No.: 10/731,421	Group Art Unit: 3762
Filed: December 09, 2003	Docket: 279.650US1

For: ENDOCARDIAL LEAD FOR A LEFT HEART CHAMBER

APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on September 1, 2006, from the Final Rejection of claims 1, 5, 7, 7-18 and 24 of the above-identified application, as set forth in the Final Office Action dated March 23, 2006.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of $500.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of pending claims.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, CARDIAC PACEMAKERS, INC..

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

The present application was filed on December 9, 2003 with claims 1-23. Claims 6 and 21-23 are cancelled. Claim 24 is added. Claims 2-4, 8, and 19-20 are withdrawn. Claims 1, 5, 7, 9-18, and 24 stand twice rejected and are the subject of the present Appeal.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Final Office Action dated March 2, 2006.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 recites a lead 100 comprising a lead body 102 extending from a proximal end 104 to a distal end 106, and an electrode 120 coupled to the lead body, wherein the lead body and the electrode each have an outer surface adapted to passively prevent formation of clots on the outer surfaces, wherein the outer surface 210 of the lead body is adapted such that a pseudo-intimal layer is formed on the outer surface when exposed to a bloodstream, and wherein the outer surface 220 of the electrode includes a textured coating including titanium microspheres. (FIGs. 1, 2, 3; and page 2, line 19-23; page 3, line 24 – page 5, line 10).

Claim 11 recites lead 500 comprising a lead body extending from a proximal end to a distal end; and an electrode 120 coupled to the lead body; wherein the lead body has a textured outer surface 510 adapted to form a pseudo-intimal layer on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface; and wherein the electrode includes an outer textured surface 220 including titanium microspheres. (FIG. 5; and page 6, lines 1 – 8; and page 4, line 23 – page 5, line 20).

Claim 17 recites a lead 100 comprising a lead body 102 extending from a proximal end 104 to a distal end 106; an electrode 120 coupled to the lead body; and means for passively preventing formation of clots on the electrode and the lead body, wherein means for passively preventing clots on the electrode includes a titanium microsphere outer surface coating 220 on at least a portion of the electrode, and wherein means for passively preventing clots on the lead body includes forming the lead body such that a pseudo-intimal layer is formed on an outer surface of the lead body when exposed to a bloodstream. (FIGs. 1, 2, 3; page 2, line 19-23; page 3, line 24 – page 5, line 10; and FIG. 4, page 5, lines 11 – 29); and FIG. 5, lines 1-20).

This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to the appended claims and its legal equivalents for a complete statement of the invention.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether Claims 1, 5, 7, 9, 10, and 24 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon (U.S. Patent No. 5,861,023) in view of McAuslan (U.S. Patent No. 4,836,884) and Helland et al. (U.S. Patent No. 5,318,572).

Whether Claims 17 and 18 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon (U.S. Patent No. 5,861,023) in view of McAuslan (U.S. Patent No. 4,836,884) and Helland et al. (U.S. Patent No. 5,318,572).

Whether Claims 11-16 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Mar et al. (U.S. Patent No. 5,411,544) and in view of McAuslan is new (U.S. Patent No. 4,836,884) and Helland et al. (U.S. Patent No. 5,318,572).

7. ARGUMENT

A) The Applicable Law under 35 U.S.C. §103

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). To do that the Examiner must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *Id.*

The Fine court stated that:

> Obviousness is tested by "what the combined teaching of the references would have suggested to those of ordinary skill in the art." In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 878 (CCPA 1981)). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." ACS Hosp. Sys., 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined only if there is some suggestion or incentive to do so." Id. (emphasis in original).

The M.P.E.P. adopts this line of reasoning, stating that:

> In order for the Examiner to establish a prima facie case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. M.P.E.P. § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed.Cir. 1991)).

B) Discussion of the rejection of claims 1, 5, 7, 9, 10, and 24, which were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon (U.S. Patent No. 5,861,023) in view of McAuslan (U.S. Patent No. 4,836,884) and Helland et al. (U.S. Patent No. 5,318,572).

Appellant traverses the obviousness rejection of claim 1. Claim 1 was improperly rejected since the references do not teach or suggest all the claim limitations and there is no suggestion to combine the references as suggested by the Examiner.

Applicant believes claim 1 is not obvious in view of the cited references since, even if combined, the references do not include each limitation recited in the claim. For instance, Applicant cannot find in the cited combination a lead "wherein the outer surface of the lead body is adapted such that a pseudo-intimal layer is formed on the outer surface when exposed to a bloodstream," as recited in claim 1. In contrast, Vachon discusses an implantable lead which includes material "for minimizing adhesion and tissue ingrowth." (Abstract). Helland does not describe anything about the lead body outer surface. The McAuslan reference discusses a modified implantable hydrogel. (Abstract). But nowhere in the McAuslan reference is the modified hydrogel specifically discussed as being applied to a lead body.

The Examiner points to Col. 2, lines 24-27 and 49-51 of McAuslan for this subject matter. However, these sections discuss, in general, implantable material that can be treated to have enhanced endothelial attachment properties. It does not discusses an "outer surface of the lead body is adapted such that a pseudo-intimal layer is formed on the outer surface when exposed to a bloodstream," as recited in the claim.

Moreover, Applicant traverses the combination of the cited references since there is no suggestion or motivation in the art to combine the references as suggested by the Office Action. Again, Vachon discusses a lead constructed to minimize adhesion and tissue ingrowth (Abstract), and McAuslan discusses a modified hydrogel to stimulate the attachment and growth of cells thereto. (Abstract). Accordingly, one of skill in the art would not be motivated to combine McAuslan with the Vachon reference. Combining McAuslan with Vachon by altering Vachon to include the hydrogel of McAuslan would destroy the stated purpose of Vachon, which is to minimize "adhesion and tissue ingrowth." (Abstract). Applicant notes that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended

purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984); MPEP § 2143.01.

Regarding the Helland reference, Helland discusses an electrode designed for promoting tissue ingrowth. (Col. 3, line 15). In contrast, as discussed above, Vachon discusses a lead constructed to minimize adhesion and tissue ingrowth (Abstract). Thus, there is no motivation in the art to modify Vachon in view of Helland.

Moreover, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990); MPEP § 2143.01. Here, the Examiner has provided hindsight analysis which completely ignores the stated purpose and function of the primary reference, Vachon, so as to piece together an obviousness rejection. There is no indication in the references themselves of any problems with Vachon that the other references allegedly solve. Accordingly, the Examiner's hindsight analysis is the only supposed motivation of combining the references.

Claims 5, 7, 9, 10, and 24 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

C) Discussion of the rejection of claims 17 and 18, which were rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon (U.S. Patent No. 5,861,023) in view of McAuslan (U.S. Patent No. 4,836,884) and Helland et al. (U.S. Patent No. 5,318,572).

Appellant traverses the obviousness rejection of claim 17. Claim 17 was improperly rejected since the references do not teach or suggest all the claim limitations and there is no suggestion to combine the references as suggested by the Examiner.

For instance, Applicant cannot find in the cited combination a lead including means for passively preventing clots on the lead body that includes forming the lead body such that a pseudo-intimal layer is formed on an outer surface of the lead body when exposed to a bloodstream, as recited in claim 17. As discussed above, Vachon discusses an implantable lead which includes material "for minimizing adhesion and tissue ingrowth." (Abstract). McAuslan

discusses a modified hydrogel, and Helland does not describe anything about the lead body outer surface.

Again, Applicant traverses the combination of the cited references since there is no suggestion in the art to combine the references as suggested by the Office Action. As noted, Vachon discusses a lead constructed to minimize adhesion and tissue ingrowth, while Helland discusses an electrode for promoting tissue ingrowth, and McAuslan discusses an implantable hydrogel to stimulate the attachment and growth of cells thereto. Accordingly, one of skill in the art would not be motivated to combine either the Helland or McAuslan reference with the Vachon reference.

Claim 18 includes each limitation of its parent claim and is therefore also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

D) Discussion of the rejection of claims 11-16, which were rejected under 35 U.S.C. § 103(a) as being unpatentable over Mar et al. (U.S. Patent No. 5,411,544) and in view of McAuslan is new (U.S. Patent No. 4,836,884) and Helland et al. (U.S. Patent No. 5,318,572).

Applicant traverses the rejection of claims 11-16. Applicant believes claim 11 is not obvious in view of the cited references since, even if combined the references do not include each limitation recited in the claim, and there is no suggestion in the art to modify Mar in view of the cited references.

For instance, Applicant cannot find in the cited combination a lead "wherein the lead body has a textured outer surface adapted to form a pseudo-intimal layer on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface," as recited in claim 11. In contrast, Mar discusses an implantable lead which includes etching to "help adhere the electrode in a specific and desirable location in the heart." (Col. 3, lines 35-36). The McAuslan reference discusses a modified implantable hydrogel. (Abstract). But nowhere in the McAuslan reference is the modified hydrogel specifically discussed as being applied to a lead body. Helland does not describe anything about the lead body outer surface.

Moreover, there is no suggestion or motivation in the art to modify the Mar reference as suggested by the Examiner. The Mar reference discusses a lead modified to "promote fibrosis." (Col 3, line 38). As noted above, Mar states this will "help adhere the electrode in a specific and

desirable location in the heart." (Col. 3, lines 35-36). However, the McAuslan discussion of a modified implantable hydrogel teaches away from promoting fibrosis. Accordingly, there is no suggestion or motivation to combine the cited references.

Claims 12-16 include each limitation of their parent claim and are also not obvious in view of the cited references. Reconsideration and allowance is respectfully requested.

8. SUMMARY

For the reasons argued above, claims 1, 5, 7, 9-18, and 24 were not properly rejected under § 103. It is respectfully submitted that the art cited does not render the claims obvious and the claims are patentable over the cited art. Reversal of the rejection and allowance of the pending claims is respectfully requested.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 2 day of April 2007.

Name

Signature

CLAIMS APPENDIX

1. A lead comprising:

a lead body extending from a proximal end to a distal end; and

an electrode coupled to the lead body;

wherein the lead body and the electrode each have an outer surface adapted to passively prevent formation of clots on the outer surfaces, wherein the outer surface of the lead body is adapted such that a pseudo-intimal layer is formed on the outer surface when exposed to a bloodstream, and wherein the outer surface of the electrode includes a textured coating including titanium microspheres.

5. The lead of claim 1, wherein the titanium microspheres have a diameter of between 75-100 μm.

7. The lead of claim 1, wherein the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface.

9. The lead of claim 1, wherein the outer surface of the lead does not include any active coatings which elute from the surface to minimize clotting.

10. The lead of claim 1, wherein the lead is adapted to be coupled to a pulse generator and is adapted for delivering cardiac resynchronization therapy.

11. A lead comprising:

a lead body extending from a proximal end to a distal end; and

an electrode coupled to the lead body;

wherein the lead body has a textured outer surface adapted to form a pseudo-intimal layer on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface; and

wherein the electrode includes an outer textured surface including titanium microspheres.

12. The lead of claim 11, wherein the electrode outer surface is adapted to trap blood cells within the textured surface to form a layer of blood cells on the electrode surface.

13. The lead of claim 11, wherein the titanium microspheres have a diameter of between 75-100 μm.

14. The lead of claim 11, wherein the outer surface of the lead does not include any active coatings which elute from the surface to minimize clotting.

15. The lead of claim 11, wherein the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface.

16. The lead of claim 11, wherein the lead is adapted to be coupled to a pulse generator and is adapted for delivering cardiac resynchronization therapy.

17. A lead comprising:

a lead body extending from a proximal end to a distal end;

an electrode coupled to the lead body; and

means for passively preventing formation of clots on the electrode and the lead body, wherein means for passively preventing clots on the electrode includes a titanium microsphere outer surface coating on at least a portion of the electrode, and wherein means for passively preventing clots on the lead body includes forming the lead body such that a pseudo-intimal layer is formed on an outer surface of the lead body when exposed to a bloodstream.

18. The lead of claim 17, wherein the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface.

24. The lead of claim 1, wherein the electrode includes a tip electrode.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.